Attachment #13

[redacted]

From: "Troutman, Joanne" <joatroutma@state.pa.us>
To: [redacted]
Sent: Friday, November 14, 2003 3:26 PM
Subject: FW: Reposting of Serous Adverse Events to the FDA

I have been directed by counsel to put this matter on January's Agenda for discussion by the Board.

-----Original Message-----
From: [redacted] [mailto:
Sent: Sunday, November 09, 2003 01:36 PM
To: ST-MEDICINE@state.pa.us
Cc: [redacted]
Subject: Reposting of Serous Adverse Events to the FDA

Joanne Troutman
Administrator
Pennsylvania State Board of Medicine

Dear Administrator Troutman,

My daughter [redacted] at age 9, after 3 injections of a new drug, was admitted to the hospital diagnosed with frank diabetes. In an effort, to see if there was any relationship between the drug and the serious adverse event, I was dumbfounded to learn that doctors are under no mandate, policy or regulation to report the occurrence of a serious adverse event (life-threatening, hospitalization, life-long) to the FDA. I of course am in concurrence, that adverse event reporting (headaches, fever, vomiting or the like) would be unrealistic.

To be a little more specific, my daughters endocrinologist promptly reported the event to the manufacturer of the drug, but would not even after my specific request that he so through MedWatch to the FDA.

The FDA, being responsible for overseeing the safety of drugs, (especially concerned with new drugs and children) cannot possibly make rational decisions based upon insufficient or not forthcoming information.

Could you kindly provide me with the reasoning for no regulation? If the doctors believe it is important enough to submit a written report to the manufacturer and I suspect it would take any longer to submit one to the FDA via MedWatch.

Please advise. Thank you for your time and consideration. [redacted]